Supporting Statement for Paperwork Reduction Act Submissions
Application for Permit to Export Controlled Substances – DEA Form 161, Application for Permit to Export Controlled Substances for Subsequent Re-export – DEA Form 161R, Application for Permit to Export Controlled Substances for Subsequent Re-export Among Members of the European Economic Area – DEA Form 161R–EEA
OMB Approval # 1117-0004

The Drug Enforcement Administration (DEA) seeks approval by the Office of Management and Budget (OMB) for a revision of an existing collection of information that was previously approved by OMB – OMB Approval# 1117-0004, Application for Permit to Export Controlled Substances – DEA Form 161, Application for Permit to Export Controlled Substances for Subsequent Re-export – DEA Form 161R, Application for Permit to Export Controlled Substances for Subsequent Re-export Among Members of the European Economic Area – DEA Form 161R–EEA.

Part A. Justification

1. Necessity of Information:

Section 1003 of the Controlled Substances Import and Export Act (21 U.S.C. 953) and Title 21, Code of Federal Regulations (21 CFR), Sections 1312.21 and 1312.22 require that any person who desires to export or re-export controlled substances listed in Schedules I or II, any narcotic substance listed in Schedules III or IV, or any non-narcotic substance in Schedule III which the Administrator has specifically designated by regulation in §1312.30, or any non-narcotic substance in Schedule IV or V which is also listed in Schedule I or II of the Convention on Psychotropic Substances, must have an export permit. To obtain the export permit, an application for the permit must be made by electronic filing to DEA on DEA Form 161 for exports, DEA Form 161R for re-exports to countries that are not members of the European Economic Area, and Form 161R-EEA for re-exports among members of the European Economic Area.

2. Needs and Uses:

These forms and the information collection help maintain a closed system of distribution. DEA Form 161, Application for Permit to Export Controlled Substances, DEA Form 161R, Application for Permit to Export Controlled Substances for Subsequent Re-export, and DEA Form 161R–EEA, Application for Permit to Export Controlled Substances for Subsequent Re-export Among Members of the European Economic Area, are intended to enable DEA to monitor and control the export of certain controlled substances to other countries. This information is also necessary for DEA to prepare a Permit to Export, DEA Form 236, which is required in order to lawfully export specific controlled substances. The permit for exportation and re-exportation of specific controlled substances enables DEA to enforce the Controlled Substances Import and Export Act.

Through § 1312.22, DEA requires that within 30 calendar days after a controlled substance is

released by a customs officer at the port of export from the United States in accordance with the permitting process, or within 10 calendar days after receipt of a written request by the Administration to the exporter, whichever is sooner, the exporter must file a report with the Administration utilizing the secure network application available on DEA's Diversion Control Division Web site that such export has occurred and the specifics of the transaction. The report must include information relating to key dates of the transaction(s) and actual quantities involved in the export process.

DEA Form 161R–EEA, "Application for Permit to Export Controlled Substances for Subsequent Re-export Among Members of the European Economic Area," is used by registrants who export controlled substances for re-export among members of the European Economic Area. Specifically, in § 1312.22, DEA is requires within 30 calendar days after the controlled substance is released by a customs officer at the port of export the exporter to file a report with the Administration through DEA's Diversion Control Division secure network application of the particulars of the transaction. Furthermore, the exporter must file similar return information within 30 days of the controlled substances being exported from the first country to the second country and for each subsequent re-export among members of the European Economic Area.

3. Use of Information Technology:

Pursuant to § 1312.22, DEA requires applicants for a permit to export controlled substances to access, complete, and submit DEA Forms 161, 161R, and 161R-EEA, and associated return information, as appropriate, through DEA's Diversion Control Diversion secure network application. Currently, 100% of DEA Forms 161, 161R, and 161R-EEA are submitted electronically.

DEA transmits the original permit to the pertinent foreign competent national authorities. The "copies" issued by DEA to registrants are only accessible through DEA Diversion Control Division's secure network application.

4. Efforts to Identify Duplication:

DEA has made efforts to identify and prevent duplication of the collection of information. DEA Forms 161, 161R, 161R-EEA are not duplicative. The collection of this information is unique to DEA.

5. Impact on Small Businesses or Entities:

DEA does not anticipate any additional impact on small business or other small entities since the last approval of this form. The revised collection will not have a significant economic impact on small business or other small entities within the meaning and intent of the Regulatory Flexibility Act, 5 U.S.C. 601-612.

6. Consequences of Less Frequent Collection:

Information is provided by registrants each time registrants propose to export or re-export certain

controlled substances and therefore cannot be collected less frequently. The Attorney General may authorize any controlled substance that is in schedule I or II, or is a narcotic drug in schedule III or IV, to be exported from the United States to a country for subsequent export from that country to another country. Within 30 days after the controlled substance is exported from the first country to the second country, the person who exported the controlled substance from the United States delivers to the Attorney General documentation certifying that such export from the first country has occurred. 21 USC 953(f)(6). This is required by statute. Failure to collect the information would impair DEA's enforcement of the statute and compliance with requirements under international treaties. Businesses and other for-profit entities participating in this information collection maintain the requested data as part of usual and customary business practices.

7. Special Circumstances Influencing Collection:

There are no special circumstances applicable to this information collection.

8. Consultation with persons outside the Agency:

Public comment was solicited in the 60-Day Notice of Information Collection published in the *Federal Register* at 85 FR 34240, on June 3, 2020. DEA received no comments concerning this collection. DEA has also published a 30-Day Federal Register Notice of Information Collection on August 10, 2020 at 85 FR 48267.

DEA meets regularly with the affected industry to discuss policies, programs, and regulations. These meetings provide an open forum to discuss matters of mutual concern with representatives of those entities from whom the information is obtained.

9. Payment or Gift to Claimants:

This collection of information does not propose to provide any payment or gift to respondents.

10. Assurance of Confidentiality:

Information requested in this collection may be considered confidential business information if marked as such in accordance with 28 CFR 16.8(c) and Exemption 4 of the Freedom of Information Act (FOIA). Submitters who are required to furnish commercial or financial information to the government are protected from the competitive disadvantages that could result from disclosure of such information. This information is protected by DEA through secure storage, limited access, and federal regulatory and DEA procedures. In the event a FOIA request is made to obtain information that has been designated as confidential business information in accordance with 28 CFR 16.8(c) and Exemption 4 of FOIA, DEA will give written notice to the submitter to allow an opportunity to object within a reasonable time prior to any disclosure by DEA.

11. Justification for Sensitive Questions:

This collection of information does not ask any questions of a sensitive nature.

12. Estimate of Hour Burden:

DEA Forms 161, 161R, and 161R-EEA are submitted on an as-needed basis by registrants who desire to obtain a permit to export or re-export controlled substances listed in schedules I or II, any narcotic substance listed in schedules III or IV, or any non-narcotic substance in schedule III which the Administrator has specifically designated by regulation in §1312.30, or any non-narcotic substance in schedule IV or V which is also listed in schedule I or II of the Convention on Psychotropic Substance.

	Number of Annual Respondents *	Number of Annual responses	Average Time per Response	Total Annual Hours
DEA-161	127	6,493	0.5	3,247
DEA-161R/161R-EEA		789	0.75	592
Total	**127**	**7,282**		**3,839**

* Based on the number of registration numbers. A respondent may use any of the three form/versions above. Separately counting the number of respondents for each form/version would result in multiple counts of the same respondent. Therefore, the number of combined respondents is used.

Total number of respondents:	127	
Number of responses per respondent per year:	57.3 386	(average)
Total annual responses	7,282	
Total annual hour burden	3,839	
Average burden, per collection:	0.527 19	
Average burden, per respondent:	30.2	

Burden dollars:

Estimate hourly wage ($/hour):[1]	$45.46
Load for benefits (percent of labor rate):[2]	42.7%
Loaded labor rate ($/hour):[3]	$64.87

Burden by form	DEA 161	DEA 161R/ 161R-EEA	Total
Number of responses	6,493	789	7,282

1 Median hourly wage, Bureau of Labor Statistics, Occupational and Employment and Wages, May 2019, 11-3071 Transportation, Storage, and Distribution Managers (https://www.bls.gov/oes/current/oes_nat.htm).
2 Bureau of Labor Statistics, "Employer Costs for Employee Compensation – December 2019" (ECEC) reports that average benefits for private industry is 29.9% of total compensation. The 29.9% of total compensation equates to 42.7% (29.9% / 70.1%) load on wages and salaries.
3 $45.46 x (1 + 0.427) = $64.87.

Burden per response (hour)	0.50	0.75	N/A
Total burden hours	3,247	592	3,839
Burden dollars per response ($)	32.44	48.65	N/A
Total burden dollars ($)	**210,633**	**38,385**	**249,018**

13. Estimate of Cost Burden:

The estimated annual cost burden is zero. Respondents are not estimated to incur any a) additional start-up cost or capital expenditure, or b) additional operation and maintenance costs or purchase services as a result of this information collection.

14. Estimated Annualized Cost to Federal Government:

Estimated Annual Labor Cost to Government:

Labor Category	Number	Annual rate ($)*	Load**	% of time	Cost ($)
Staff Coordinator - GS-14	1	137,491	1.605	25%	55,168
Program Analyst - GS-13	1	116,353	1.605	60%	112,048
Import/Export Specialist - GS-13	2	116,353	1.605	25%	93,373
Total					**260,589**

*Government salary figures are based on Washington, DC locality pay at step 5 for each grade level.
**Load of 60.5% for benefits based on the ECEC for "State and local government." The ECEC does not include figures for the Federal Government.

Total cost to government: $260,589

All costs are recovered from registrants through registration fees, as required by the CSA. 21 U.S.C. 886a.

15. Reasons for Change in Burden:

The increase in annual responses and annual burden hours reflect adjustments related to normal business activity. The decrease in the annual cost is due to the elimination of paper response shipping cost, which were included in the 2017 annual cost figure, as responses have moved to electronic responses. There have been no statutory or regulatory changes affecting this information collection. The table below summarizes the changes since the last renewal of this information collection.

	2017 Approved Burden	2020 Requested Burden	Difference
Annual responses	6,116	7,282	1,166

Annual burden hours	3,301	3,839	538
Annual cost ($)	281,709	249,018	(32,691)

16. Plans for Publication:

DEA will not public the results of the information collected.

17. Expiration Date of Approval:

DEA does not object to OMB displaying the expiration date.

18. Exceptions to the Certification Statement:

DEA is not seeking an exception to the certification statement “Certification for Paperwork Reduction Act Submissions” for this collection of information.

Part B. Statistical Methods

DEA does not employ statistical methods in this information collection.